

Remarks

Claims 1-22 and 137 are pending. Applicants elected to prosecute the invention of Group I - claims 1-22 and 137, drawn to a method of making dosage forms. Claims 23-136 have been canceled without prejudice to the filing of claims directed to the canceled subject matter in this or a related application. Claims 1 and 21 have been amended to eliminate the reference to direct engagement and replaced with a description that more closely follows the terminology in the Specification.

Claims 1 and 21 provide that the nozzle moves for injection and then retracts away to close a mold cavity. Paragraph 300 of the published Specification provides that:

"Accordingly, during operation of the thermal setting molding module 400, nozzles 410 **move** up during rotation of the thermal setting molding module 400 and **inject** a starting material into molding chambers 422. Next, starting material is hardened within the molding chambers 422 into shaped pellets. Nozzles 410 are then **retracted** from the molding chambers. All of this occurs as the molding chambers 422 and nozzles 410 are rotating. After the starting material has hardened into shaped pellets, it is ejected from the molding chambers. See FIGS. 87 and 88."

Paragraph 180 of the published Specification provides that:

"The thermal cycle molding module avoids these problems. It employs nozzle systems (referred to herein as valve assemblies) each comprising a valve body, valve stem and valve body tip. After injection of flowable material into the mold cavity, the valve body tip **closes the mold cavity while conforming seemlessly [sic "conforming seamlessly"] to the shape of the mold cavity**. This technique eliminates visible defects in the molded product and also allows a wide range of heretofore unmoldable or difficult to mold materials to be used. Moreover, use of the thermal cycle molding module according to the invention avoids the production of scrap flowable material, in that substantially all of the flowable material becomes part of the finished product."

Word for word precision is not required. In this case, the Specification unquestionably provides adequate support for movement and retraction away from and closing of the mold cavity as now recited in claims 1 and 21. No new matter has been added.

The Examiner rejects claims 1-12, 20, 21 and 137 under 35 U.S.C. 103 as being unpatentable over U.S. Patent No. 6,669,883 ("Rosenberg et al.") in view of U.S. Patent No. 5,229,164 ("Pins et al."). Applicants respectfully traverse this rejection.

Claims 1 and 21 provide that flowable material is injected through a nozzle that moves into position for injection, injects the flowable material, and then retracts away to close a mold cavity. The most significant point in the Examiner's rejection is the assertion that extruded material is readable on the claimed step of injecting into a mold cavity. Rosenberg does not disclose an extrusion other than to say such could be used in combination with the counter-rotating molding wheels. Nonetheless, an extrusion system does not have a nozzle that moves relative to a mold cavity for injecting flowable material into said mold cavity as required by the claims 1 and 21.

The Examiner cites Pins for the proposition that it is known to mold a dosage form by injecting through a nozzle into a mold cavity using direct engagement. Presumably the Examiner would rely upon the same reference to address the newly added elements of the claimed invention. Pins relates to a process for producing individually dosed administration forms. Pins describes a system wherein materials are softened and then deposited into open forms and allow the material to harden into a desired dosage form.

The manufacturing systems taught in Rosenberg and Pins operate in fundamentally different ways to produce their end products. These references are not combinable because they are not taken from analogous arts or intended to solve similar problems. The Examiner is essentially suggesting that one skilled in the art would make a wholesale conversion the counter-rotating system shown in Rosenberg into the drop deposit system shown in Pins. Given that the feed system in Rosenberg is a solid, it seems unreasonable to believe that counter-rotating wheels would be replaced with drop deposit substrates for materials shown in Pins. For these reasons, Applicants request that the Examiner reconsider and withdraw his obviousness rejection based on Rosenberg and Pins.

Claim 10 provides that the flowable material comprises gelatin. The specification notes that gelatin is an extremely different material to use as an injection molded material for making dosage forms. Gelatins, once hydrated, have a very abrupt transition temperature between the liquid and solid/gel phases. See publication of instant application, US

2003/0086973 A1, paragraph 173. Gelatins are fundamentally different from thermoplastics in this regard. Consequently, it has not been known for such use in this field.

The Examiner indicates that, with respect to claim 10, Applicants should refer to column 4, line 26. The sentence provided in that passage provides: "The glass transition temperature of the mixture must therefore be below 180°C, preferably below 130°C." The passage does not provide any suggestion or motivation for one skilled in the art to utilize gelatin as a flowable material.

The Examiner rejects claims 14-19 and 22 under 35 U.S.C. 103 as being unpatentable over Rosenberg in view of U.S. Patent No. 6,177,125 ("Voss"). Applicants respectfully traverse this rejection.

Voss is cited for the proposition of providing inserts in the mold cavity prior to injection of the flowable material. Notwithstanding the absence or showing in Voss of inserts, Rosenberg fails to disclose the essential feature of claims 1 and 22 that flowable material is injected through a nozzle that moves into position for injection, injects the flowable material, and then retracts away to close a mold cavity. All of the arguments above are incorporated herein by reference. For substantially the same reasons above, Applicants request that the Examiner reconsider and withdraw his obviousness rejection of claims 14-19 and 22 in view of Rosenberg and Voss.

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Applicants submit that the present application is now in condition for allowance.
Applicants request that the Examiner contact the undersigned representative if minor
amendments will further prosecution towards issuance.

Respectfully submitted,

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